

Office of Healthcare Inspections

Report No. 13-00026-196

Community Based Outpatient Clinic Reviews at Edith Nourse Rogers Memorial Veterans Hospital Bedford, MA

May 14, 2013

Why We Did This Review

The VA OIG is undertaking a systematic review of the VHA's CBOCs to assess whether CBOCs are operated in a manner that provides veterans with consistent, safe, high-quality health care.

The Veterans' Health Care Eligibility Reform Act of 1996 was enacted to equip VA with ways to provide veterans with medically needed care in a more equitable and cost-effective manner. As a result, VHA expanded the Ambulatory and Primary Care Services to include CBOCs located throughout the United States. CBOCs were established to provide more convenient access to care for currently enrolled users and to improve access opportunities within existing resources for eligible veterans not currently served.

Veterans are required to receive one standard of care at all VHA health care facilities. Care at CBOCs needs to be consistent, safe, and of high quality, regardless of model (VA-staffed or contract). CBOCs are expected to comply with all relevant VA policies and procedures, including those related to quality, patient safety, and performance.

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Glossary

C&P credentialing and privileging

CBOC community based outpatient clinic

CDC Centers for Disease Control and Prevention

EHR electronic health record

EOC environment of care

FPPE Focused Professional Practice Evaluation

FY fiscal year

MH Mental Health

NCP National Center for Health Promotion and

Disease Prevention

NC noncompliant

OIG Office of Inspector General

PII personally identifiable information

VHA Veterans Health Administration

VISN Veterans Integrated Service Network

WH women's health

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Executive Summary

Purpose: We evaluated select activities to assess whether the CBOCs operated in a manner that provides veterans with consistent, safe, high-quality health care.

We conducted an onsite inspection of the CBOC during the week of March 11, 2013.

The review covered the following topic areas:

- WH
- Vaccinations
- C&P
- EOC
- Emergency Management

For the WH and vaccinations topics, EHR reviews were performed for patients who were randomly selected from all CBOCs assigned to the parent facility. The C&P, EOC, and emergency management onsite inspections were only conducted at the randomly selected CBOC (see Table 1).

VISN	Facility	CBOC Name	Location
1	Edith Nourse Rogers Memorial Veterans Hospital	Gloucester	Gloucester, MA
Table 1. Sites Inspected			

Review Results: We made recommendations in two review areas.

Recommendations: The VISN and Acting Facility Director, in conjunction with the respective CBOC managers, should take appropriate actions to:

- Ensure that the ordering provider or surrogate is notified of normal cervical cancer screening results within the allotted timeframe and that notification is documented in the EHR.
- Ensure that patients with normal cervical cancer screening results are notified of results within the defined timeframe and that notification is documented in the EHR.
- Ensure that the WH Liaisons collaborate with the Women Veterans Program Manager.

- Ensure that laboratory specimens are secured during transport from the CBOCs to the parent facility to prevent disclosure of patients' PII.
- Ensure that EOC deficiencies and corrective actions are tracked and trended by the EOC Committee.

Comments

The VISN and Facility Directors agreed with the CBOC review findings and recommendations and provided acceptable improvement plans. (See Appendixes A and B, pages 11–14, for the full text of the Directors' comments.) We will follow up on the planned actions until they are completed.

JOHN D. DAIGH, JR., M.D. Assistant Inspector General for Healthcare Inspections

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Objectives and Scope

Objectives

- Evaluate whether CBOCs comply with selected VHA requirements regarding the provision of cervical cancer screening, results reporting, and WH liaisons.
- Evaluate whether CBOCs properly provided selected vaccinations to veterans according to CDC guidelines and VHA recommendations.
- Determine whether CBOC providers are appropriately credentialed and privileged in accordance with VHA Handbook 1100.19.¹
- Determine whether CBOCs are in compliance with standards of operations according to VHA policy in the areas of environmental safety and emergency planning.²

Scope and Methodology

Scope

We reviewed selected clinical and administrative activities to evaluate compliance with requirements related to patient care quality and the EOC. In performing the reviews, we assessed clinical and administrative records as well as completed an onsite inspection at a randomly selected site. Additionally, we interviewed managers and employees. The review covered the following five activities:

- WH
- Vaccinations
- C&P
- EOC
- Emergency Management

Methodology

To evaluate the quality of care provided to veterans at CBOCs, we conducted EHR reviews for the WH and vaccinations topic areas. For WH, the EHR reviews consisted of a random sample of 50 women veterans (23–64 years of age). For vaccinations, the EHR reviews consisted of random samples of 75 veterans (65 and older) and 75 additional veterans (all ages), unless fewer patients were available, for tetanus and

¹ VHA Handbook 1100.19, Credentialing and Privileging, November 14, 2008.

² VHA Handbook 1006.1, Planning and Activating Community-Based Outpatient Clinics, May 19, 2004.

pneumococcal, respectively. The study populations consisted of patients from all CBOCs assigned to the parent facility.³

The C&P, EOC, and emergency management onsite inspections were only conducted at the randomly selected CBOC. One CBOC was randomly selected from the 56 sampled parent facilities, with sampling probabilities proportional to the numbers of CBOCs eligible to be inspected within each of the parent facilities.⁴

In this report, we make recommendations for improvement. Recommendations pertain to issues that are significant enough to be monitored by the OIG until corrective actions are implemented.

We conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

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³ Includes all CBOCs in operation before October 1, 2011.

⁴ Includes 96 CBOCs in operation before October 1, 2011, that had 500 or more unique enrollees.

CBOC Profiles

To evaluate the quality of care provided to veterans at CBOCs, we designed reviews with an EHR component to capture data for patients enrolled at all of the CBOCs under the parent facility's oversight.⁵ The table below provides information relative to each of the CBOCs under the oversight of the parent facility.

VISN	Parent Facility	CBOC Name	Locality ⁶	Uniques FY 2012 ⁷	Visits FY 2012 ⁷	CBOC Size ⁸
T drone I domey	. u.o.u. r uomiy	Gloucester (Gloucester, MA)	Urban	1,445	4,246	Small
4	Edith Nourse Rogers Memorial Veterans Hospital	Haverhill (Haverhill, MA)	Urban	2,655	9,710	Mid-Size
ין ד		Lynn/North Shore (Lynn, MA)	Urban	2,041	6,243	Mid-Size
		Winchendon (Winchendon, MA)	Rural	16	16	Small
Table 2. Profiles						

⁵ Includes all CBOCs in operation before October 1, 2011.

⁶ http://vaww.pssg.med.va.gov/

⁷ http://vssc.med.va.gov

⁸ Based on the number of unique patients seen as defined by VHA Handbook 1160.01, *Uniform Mental Health Services in VA Medical Centers and Clinics*, September 11, 2008, the size of the CBOC facility is categorized as very large (> 10,000), large (5,000-10,000), mid-size (1,500-5,000), or small (< 1,500).

WH and Vaccination EHR Reviews Results and Recommendations

WH

Cervical cancer is the second most common cancer in women worldwide.⁹ Each year, approximately 12,000 women in the United States are diagnosed with cervical cancer.¹⁰ The first step of care is screening women for cervical cancer with the Papanicolaou test or "Pap" test. With timely screening, diagnosis, notification, and treatment, the cancer is highly preventable and associated with long survival and good quality of life.

VHA policy outlines specific requirements that must be met by facilities that provide services for women veterans. We reviewed EHRs, meeting minutes and other relevant documents, and interviewed key WH employees. Table 3 shows the areas reviewed for this topic. The review elements marked as noncompliant needed improvement. Details regarding the findings follow the table.

NC	Areas Reviewed		
	Cervical cancer screening results were entered into the		
	patient's EHR.		
X	The ordering VHA provider or surrogate was notified of results		
	within the defined timeframe.		
X	Patients were notified of results within the defined timeframe.		
	Each CBOC has an appointed WH Liaison.		
X	There is evidence that the CBOC has processes in place to		
	ensure that WH care needs are addressed.		
Table 3. WH			

There were 22 patients who received a cervical cancer screening at the Edith Nourse Rogers Memorial Veterans Hospital's CBOCs.

<u>Provider Notification</u>. VHA requires that normal cervical cancer screening results must be reported to the ordering provider or surrogate within 30 calendar days of the report being issued and the notification is documented in the EHR.¹² We reviewed the EHRs of 19 patients who had normal cervical cancer screening results and did not find documentation in 7 records that the ordering provider or surrogate was notified within 30 calendar days.

⁹ World Health Organization. *Cancer of the cervix*. Retrieved from: http://www.who.int/reproductivehealth/topics/cancers/en/index.html.

¹⁰ U.S. Cancer Statistics Working Group, United States Cancer Statistics: 1999-2008 Incidence and Mortality Webbased report.

¹¹ VHA Handbook 1330.01, Health Care Services for Women Veterans, May 21, 2010.

¹² VHA Handbook 1330.01.

<u>Patient Notification of Normal Cervical Cancer Screening Results</u>. We reviewed the 19 EHRs of patients who had normal cervical cancer screening results and determined that 7 patients were not notified within the required 14 days from the date the pathology report became available.

<u>WH Liaisons</u>. We found no evidence that the WH Liaisons at the Edith Nourse Rogers Memorial Veterans Hospital's CBOCs collaborated with the parent facility's Women Veterans Program Manager.

Recommendations

- 1. We recommended that a process is established to ensure that the ordering provider or surrogate is notified of normal cervical cancer screening results within the allotted timeframe and that notification is documented in the EHR.
- 2. We recommended that managers ensure that patients with normal cervical cancer screening results are notified of results within the defined timeframe and that notification is documented in the EHR.
- **3.** We recommended that the Acting Facility Director ensures that the WH Liaisons collaborate with the Women Veterans Program Manager.

Vaccinations

The VHA NCP was established in 1995. The NCP establishes and monitors the clinical preventive services offered to veterans, which includes the administration of vaccinations.¹³ The NCP provides best practices guidance on the administration of vaccinations for veterans. The CDC states that although vaccine-preventable disease levels are at or near record lows, many adults are under-immunized, missing opportunities to protect themselves against diseases such as tetanus and pneumococcal infections.

Adults should receive a tetanus vaccine every 10 years. At the age of 65, individuals who have never had a pneumococcal vaccination should receive one. For individuals 65 and older who have received a prior pneumococcal vaccination, one-time revaccination is recommended if they were vaccinated 5 or more years previously and were less than 65 years of age at the time of the first vaccination.

We reviewed documentation of selected vaccine administrations and interviewed key personnel. Table 4 shows the areas reviewed for this topic. Details regarding the finding follow the table.

NC	Areas Reviewed
	Staff screened patients for the tetanus vaccination.
Staff administered the tetanus vaccination when indicated.	

¹³ VHA Handbook 1120.05, Coordination and Development of Clinical Preventive Services, October 13, 2009.

NC	Areas Reviewed (continued)		
	Staff screened patients for the pneumococcal vaccination.		
	Staff administered the pneumococcal vaccination when indicated.		
	Staff properly documented vaccine administration.		
Managers developed a prioritization plan for the potential occurrence of vaccine shortages.			
Table 4. Vaccinations			

<u>Documentation of Vaccinations</u>. Federal Law requires that documentation for administered vaccinations include specific elements, such as the vaccine manufacturer and lot number of the vaccine used ¹⁴. We reviewed the EHRs of 23 patients who were administered a pneumococcal vaccine at the parent facility or its associated CBOCs. We did not find documentation of all the required information related to pneumococcal vaccine administration in 10 of the EHRs where the vaccine was given before 2006. However, in late 2005, a template recommended by the VISN was introduced at the facility to correct the documentation. Generally, records of vaccines received after 2006 contained all required elements. We made no recommendations.

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¹⁴ Childhood Vaccine Injury Act of 1986 (PL 99 660) sub part C, November 16, 2010.

Onsite Reviews Results and Recommendations

CBOC Characteristics

We formulated a list of CBOC characteristics that includes identifiers and descriptive information for the randomly selected CBOC (see Table 5).

	Gloucester		
VISN	1		
Parent Facility	Edith Nourse Rogers Memorial Veterans Hospital		
Types of Providers	Nurse Practitioner Primary Care Physician		
Number of MH Uniques, FY 2012	63		
Number of MH Visits, FY 2012	565		
MH Services Onsite	Yes		
Specialty Care Services Onsite	No		
Ancillary Services Provided Onsite	Electrocardiogram Laboratory		
Tele-Health Services	No		
Table 5. Characteristics			

C&P

We reviewed C&P folders, scopes of practice, meeting minutes, and VetPro information and interviewed senior managers to determine whether facilities had consistent processes to ensure that providers complied with applicable requirements as defined by VHA policy.¹⁵ Table 6 shows the areas reviewed for this topic.

NC	Areas Reviewed			
	Each provider's license was unrestricted.			
New Provider				
	Efforts were made to obtain verification of clinical privileges			
	currently or most recently held at other institutions.			
	FPPE was initiated.			
	Timeframe for the FPPE was clearly documented.			
	The FPPE outlined the criteria monitored.			
	The FPPE was implemented on first clinical start day.			
	The FPPE results were reported to the medical staff's Executive			
	Committee.			
	Additional New Privilege			
	Prior to the start of a new privilege, criteria for the FPPE were developed.			
	There was evidence that the provider was educated about FPPE			
	prior to its initiation.			
	FPPE results were reported to the medical staff's Executive			
	Committee.			
	FPPE for Performance			
	The FPPE included criteria developed for evaluation of the			
	practitioners when issues affecting the provision of safe, high-			
	quality care were identified.			
	A timeframe for the FPPE was clearly documented.			
	There was evidence that the provider was educated about FPPE prior to its initiation.			
	FPPE results were reported to the medical staff's Executive Committee.			
	Privileges and Scopes of Practice			
	The Service Chief, Credentialing Board, and/or medical staff's			
	Executive Committee list documents reviewed and the rationale for			
	conclusions reached for granting licensed independent practitioner			
	privileges.			
	Privileges granted to providers were setting, service, and provider			
	specific.			
	The determination to continue current privileges was based in part			
	on results of Ongoing Professional Practice Evaluation activities.			
	Table 6. C&P			

¹⁵ VHA Handbook 1100.19.

The CBOC was compliant with the review areas; therefore, we made no recommendations.

EOC and Emergency Management

<u>EOC</u>

To evaluate the EOC, we inspected patient care areas for cleanliness, safety, infection control, and general maintenance. We reviewed relevant documents and interviewed key employees and managers. Table 7 shows the areas reviewed for this topic. The review elements marked as noncompliant needed improvement. Details regarding the findings follow the table.

NC	Areas Reviewed		
	The CBOC was Americans with Disabilities Act-compliant, including:		
	parking, ramps, door widths, door hardware, restrooms, counters		
	The CBOC was well maintained (e.g., ceiling tiles clean and in good		
	repair, walls without holes, etc.).		
	The CBOC was clean (walls, floors, and equipment are clean).		
	Material safety data sheets were readily available to staff.		
	The patient care area was safe.		
	Access to fire alarms and fire extinguishers was unobstructed.		
	Fire extinguishers were visually inspected monthly.		
	Exit signs were visible from any direction.		
	There was evidence of fire drills occurring at least annually.		
	Fire extinguishers were easily identifiable.		
	There was evidence of an annual fire and safety inspection.		
	There was an alarm system or panic button installed in high-risk		
	areas as identified by the vulnerability risk assessment.		
	The CBOC had a process to identify expired medications.		
	Medications were secured from unauthorized access.		
	Privacy was maintained.		
	Patients' personally identifiable information was secured and protected.		
X	Laboratory specimens were transported securely to prevent unauthorized access.		
	Staff used two patient identifiers for blood drawing procedures.		
	Information Technology security rules were adhered to.		
	There was alcohol hand wash or a soap dispenser and sink available		
	in each examination room.		
	Sharps containers were less than 3/4 full.		
	Safety needle devices were available for staff use (e.g., lancets,		
	injection needles, phlebotomy needles).		
X	The CBOC was included in facility-wide EOC activities.		
	Table 7. EOC		

<u>PII</u>. We found that the transportation of laboratory specimens from the Gloucester CBOC to the parent facility did not ensure the security of patients' PII. CBOC staff placed the specimens in an unlocked zippered bag, and a facility passenger shuttle bus transported the specimens to the parent facility for processing. The specimen labels contained patients' PII and because the bag was not locked; staff could not ensure the security of patients' PII.¹⁶

<u>Facility-Wide EOC Activities</u>. EOC rounds were regularly performed at the Gloucester CBOC and appropriate corrective actions were taken. However, deficiencies and corrective actions were not tracked and trended by the EOC Committee.

Recommendations

- **4**. We recommended that laboratory specimens be secured during transport from CBOCs to the parent facility to prevent the disclosure of patients' PII.
- **5**. We recommended that all identified EOC deficiencies and corrective actions be tracked and trended by the EOC Committee.

Emergency Management

VHA policy requires each CBOC to have a local policy or standard operating procedure defining how medical and MH emergencies are handled.¹⁷ Table 8 shows the areas reviewed for this topic.

NC	Areas Reviewed	
	There was a local medical emergency management plan for this	
	CBOC.	
	The staff articulated the procedural steps of the medical emergency	
	plan.	
	The CBOC had an automated external defibrillator onsite for cardiac	
	emergencies.	
	There was a local MH emergency management plan for this CBOC.	
	The staff articulated the procedural steps of the MH emergency	
	plan.	
Table 8. Emergency Management		

The CBOC was compliant with the review areas; therefore, we made no recommendations.

¹⁶ The Health Insurance Portability and Accountability Act (HIPAA), 1996.

¹⁷ VHA Handbook 1006.1.

VISN 1 Director Comments

Department of Veterans Affairs

Memorandum

Date: April 19, 2013

From: Director, VISN 1 (10N1)

Subject: CBOC Reviews at Edith Nourse Rogers Memorial

Veterans Hospital

To: Director, Bedford Regional Office of Healthcare Inspections

(54BN)

Acting Director, Management Review Service (VHA 10AR

MRS OIG CAP CBOC)

I have reviewed and concur with the action plans regarding the Community Based Outpatient Clinic review at Edith

Nourse Rogers Memorial Veterans Hospital.

(original signed by:)

Glen Gechlik, MD

Acting Deputy Network Director

Edith Nourse Rogers Memorial Veterans Hospital Acting Director Comments

Department of Veterans Affairs

Memorandum

Date: April 19, 2013

From: Acting Director, Edith Nourse Rogers Memorial Veterans

Hospital (518/00)

Subject: CBOC Reviews at Edith Nourse Rogers Memorial

Veterans Hospital

To: Director, VISN 1 (10N1)

We concur with the findings of this review. Action plans for all Recommendations for Improvement have been developed. As of April 19th, four recommendations have already been corrected and are being monitored for sustainment.

Improvement Action Plan for the remaining one recommendation will be fully implemented by May 31, 2013.

(original signed by:)

Dan Berlowitz

Acting Chief of Staff/Acting Hospital Director

Comments to OIG's Report

The following Acting Director's comments are submitted in response to the recommendations in the OIG report:

OIG Recommendations

1. We recommended that a process is established to ensure that the ordering provider or surrogate is notified of normal cervical cancer screening results within the allotted timeframe and that notification is documented in the EHR.

Concur

Target date for completion: April 19, 2013

There is a process in place for provider notification of cervical cancer screening results. The results of the cervical cancer screenings are entered in the electronic health record and the ordering provider gets a view alert via the electronic record as soon as the results are available. Documentation in the electronic health record will be recorded by providers when notification to the Veteran is made by telephone, in person, or by letter in CPRS. This will serve as documentation that they have received the notification.

The Primary Care Service Line Manager will track and monitor up to 5 charts each month from designated WH providers of cervical cancer screenings to ensure there is receipt of notification documented in the electronic health record within the appropriate timeframe. For providers who order less than 5 pap smears per month, all cases will be reviewed. The results of the monitor will be reported to the Primary Care PIC and results will be shared with the Women Veterans Advisory Counsel for compliance.

2. We recommended that managers ensure that patients with normal cervical cancer screening results are notified of results within the defined timeframe and that notification is documented in the EHR.

Concur

Target date for completion: April 19, 2013

The same Medical Letter template will also serve as the letter which is sent to the Veteran as notification of the results.

The Primary Care Service Line Manager will track and monitor up to 5 charts each month from designated WH providers who order cervical cancer screenings to ensure there is timely documentation of patient notification. For providers who order less than 5 pap smears per month, all cases will be reviewed. The results of the monitor will be reported to the Primary Care PIC and results will be shared with the Women Veterans Advisory Counsel for compliance.

3. We recommended that the Acting Facility Director ensures that the WH Liaisons collaborate with the Women Veterans Program Manager.

Concur

Target date for completion: April 19, 2013

The WVPM will collaborate with the CBOC liaisons by participating in the Women Veterans Advisory Council meetings via telephone to discuss specific issues at the various CBOCs that need attention. The WVPM will also have face to face contacts with the liaisons during routine CBOC Environment of Care rounds conducted at CBOCs along with the findings of these rounds. The newly appointed Women Veterans Program Director will also serve as a point of contact between the liaisons and the WVPM, as needed.

4. We recommended that laboratory specimens are secured during transport from the CBOCs to the parent facility to prevent the disclosure of patients' PII.

Concur

Target date for completion: May 31, 2013

To secure the specimens during transport between facilities, heavy duty padlocks locks will be distributed to the Gloucester, Haverhill, and Lynn CBOCS to secure the zippers on the coolers. They will also be used for the coolers going from Bedford to West Roxbury. Coolers arriving at the Bedford lab or at the West Roxbury lab, with the padlocks intact, will be considered secured during the transport process. This process will be monitored by adding a check off column to the lab transport log already in place to verify that the cooler arrived with lock in place.

5. We recommended that all identified EOC deficiencies and corrective actions be tracked and trended by the EOC Committee.

Concur

Target date for completion: April 19, 2013

Effective immediately, all Scheduled Environmental Rounds Conducted at the CBOC's will be reviewed at the Post-Inspection Month, EOC Meeting. All deficiencies will be recorded, tracked with a starting date and a required completion date to include a plan to correct if work cannot be done within 14 days. Report will include the correcting official. Also the CBOC Manager responsible for the Clinic will have access to the SharePoint Rounds site.

OIG Contact and Staff Acknowledgments

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